DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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AGFA Healthcare N.V.
% Ms. Shaeann Cavanagh
Regulatory Affairs Specialist NA
AGFA Healthcare
10 South Academy Street
GREENVILLE SC 29601

June 1, 2015

Re: K143397
Trade/Device Name: ICIS View
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: April 24, 2015
Received: April 27, 2015

Dear Ms. Cavanagh:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Robert A Ochs

Robert Ochs, Ph.D.
Acting Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K143397

Device Name

ICIS® View

Indications for Use *(Describe)*

ICIS® View is a software application used for reference viewing of medical images and associated reports and, as such, fulfills a key role in Agfa HealthCare's Imaging Clinical Information System (ICIS). ICIS® View enables healthcare professionals, including (but not limited to) physicians, surgeons, nurses, and administrators to receive and view patient images and data from multiple departments and organizations within one multi-disciplinary viewer.

Users may access the product directly via a web-browser, select mobile devices, healthcare portal or within the Electronic Medical Record (EMR). ICIS® View allows users to perform basic image manipulations and measurements (for example window/level, rotation, zoom, and markups).

ICIS® View can optionally be configured for Full Fidelity mode, which is intended for diagnostic use, review and analysis of CR, DX, CT, MR, US images and medical reports. ICIS® View Full Fidelity is not intended to replace full diagnostic workstations and should only be used when there is no access to a workstation. ICIS® View full fidelity is not intended for the display of digital mammography images for diagnosis.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(K) SUMMARY
Agfa HealthCare's ICIS® View

Common Name: Picture Archiving and Communications System (PACS)
Classification Name: Radiological Image Processing System
Regulatory Classification: 21 CFR 892.2050
Product Code: LLZ
Proprietary Name: ICIS® View
Agfa HealthCare N.V.
Septestraat 27
B-2640 Mortsel
Belgium
Contact: Jodi Coleman, Prepared: November 26, 2014
Telephone: 519-746-6210 ext. 2485

A. LEGALLY MARKETED PREDICATE DEVICES

This is a 510(k) for Agfa's ICIS® View software, a picture archiving and communications system. It is substantially equivalent to systems with MIM Software Inc.'s Mobile MIM (K103785-primary predicate), Agfa HealthCare's IMPAX Workstation (K022292), and Client Outlook Inc.'s eUnity™ (K111164).

B. DEVICE DESCRIPTION

Agfa's ICIS® View system is a picture archiving and communication system (PACS), product code LLZ, intended to provide an interface for the display, annotation, review, printing, storage and distribution of multimodality medical images, reports and demographic information for review and diagnostic purposes within the system and across computer networks.

The new device is substantially equivalent to the predicate devices (K103785, K022292, & K111164). It is a multidisciplinary viewer that allows the user to securely access patient images and reports from any PACS or vendor-neutral archive. Images and reports can be viewed directly via a web-browser, select mobile device, healthcare portal or Electronic Medical Record (EMR). The new device includes some of the clinical tools of the predicate devices specifically the functionality to retrieve original lossless renditions of stored images for diagnostic purposes.

The optional Full Fidelity functionality allows the retrieval of original lossless renditions of stored CR, DX, CT, MR, and US images for diagnostic purposes on select mobile devices or FDA cleared display monitors when there is no access to a full workstation.

Principles of operation and technological characteristics of the new and predicate devices are the same. There is no change to the intended use of the device vs. the predicate devices. Laboratory data including, performance assessments and image quality evaluations conducted with qualified radiologists confirm that performance is equivalent to the predicates.

C. INTENDED USE

ICIS® View is a software application used for reference viewing of medical images and associated reports and, as such, fulfills a key role in Agfa HealthCare's Imaging Clinical

Information System (ICIS). ICIS® View enables healthcare professionals, including (but not limited to) physicians, surgeons, nurses, and administrators to receive and view patient images and data from multiple departments and organizations within one multi-disciplinary viewer.

Users may access the product directly via a web-browser, select mobile devices, healthcare portal or within the Electronic Medical Record (EMR). ICIS® View allows users to perform basic image manipulations and measurements (for example window/level, rotation, zoom, and markups).

ICIS® View can optionally be configured for Full Fidelity mode, which is intended for diagnostic use, review and analysis of CR, DX, CT, MR, US images and medical reports. ICIS® View Full Fidelity is not intended to replace full diagnostic workstations and should only be used when there is no access to a workstation. ICIS® View full fidelity is not intended for the display of digital mammography images for diagnosis.

Intended use has not changed as a result of any labeling modification(s).

D. SUBSTANTIAL EQUIVALENCE SUMMARY

Agfa's ICIS® View system has an Indications For Use statement similar to the predicate devices (K103785, K022292, & K111164). The statements have been combined and simplified. There are no changes to the intended use/indications of the device. Intended uses are the same. The devices have the same technological characteristics.

Both ICIS® View and the primary predicate device, Mobile MIM (K103785) are used to display medical images for diagnostic purposes of multiple modalities inlcuding MR and CT. Both provide wireless and portable access to medical images on select Apple products. Furthermore, ICIS® View and Mobile MIM (K103785) contain a statement that it is not intended to replace full diagnostic workstations and should only be used when there is no access to a workstation. ICIS® View and eUnity™ (K111164) are indicated to allow image manipulations and display lossy/lossless images. Both ICIS® View and predicate device, IMPAX Workstation (K022292) are indicated to display, review, transfer, store, and archive medical images. ICIS® View and all three predicate devices (K103785, K022292, & K111164) are not indicated for mammography and all the devices accept standard DICOM transfers.

The only difference of the new device and the primary predicate device, Mobile MIM (K103785), is the new device is server based software that connects to an existing PACS; whereas, Mobile MIM contains an App that connects to the existing PACS. However, the other two predicates, IMPAX Workstation (K022292) and eUnity™ (K111164) are also server based software that connects to the existing PACS. Differences in devices do not alter the intended diagnostic effect.

The devices have the same technological characteristics. The new device and the predicate devices (K103785, K022292, & K111164) are picture archiving and communication systems (PACS), Product Code LLZ. Agfa's ICIS® View system is substantially equivalent to the predicate devices (K103785, K022292, & K111164) in that it uses precisely the same technology to capture and display medical data. Descriptive characteristics and performance data are adequate to ensure equivalence.

Performance data including resolution testing and image quality evaluations by qualified radiologists are adequate to ensure equivalence.

Table 1 on the below summarizes the similarities and differences between the new device and predicate devices.

	ICIS® View (New Device)	**Mobile MIM (Primary PREDICATE-K103785)**	**IMPAX Workstation (PREDICATE-K022292)**	**eUnity™ (PREDICATE-K111164)**
Communication	Same as predicates	DICOM	DICOM	HL7, DICOM, IHE
Mammographic Use	Same as predicates	No	No	No
Modalities for Diagnostic Use	CR, DX, CT, MR, US	SPECT, PET, CT, MR	Radiology (including CR, DX, CT, MR, US)	Radiology (including CR, DX, CT, MR, US)
Operating System for Diagnostic Viewing	Windows 7 & iOS8	iOS	Windows 7 & 8	Windows & iOS
Mobile Device Support for Diagnostic Viewing	iPad® 3, iPad® 4	Apple iOS handheld devices	-	-
Transfer/Storage/Display of Medical Images	Same as predicates	Yes	Yes	Yes
Network Access	Same as K022292 & K111164	App that connects to existing PACS	Server based software, connects to existing PACS	Server based software, connects to existing PACS
User Authentification	Same as predicates	Yes	Yes	Yes
Window Level	Same as predicates	Yes	Yes	Yes
Rotate/Pan/Zoom	Same as predicates	Yes	Yes	Yes
Measurements	Same as predicates	Yes	Yes	Yes
Annotations	Same as predicates	Yes	Yes	Yes
Indications for Use Statements	ICIS® View is a software application used for reference viewing of medical images and associated reports and, as such, fulfills a key role in Agfa HealthCare's Imaging Clinical Information System (ICIS). ICIS® View enables healthcare professionals, including (but not limited to) physicians, surgeons, nurses, and administrators to receive and view patient images and data from multiple departments and	The Mobile MIM software program is used for the registration, fusion, and/or display for diagnosis of medical images from only the following modalities: SPECT, PET, CT, and MRI.	IMPAX Workstations with MPR, Digital Subtraction and 3D options are intended for use in the acquisition, display, digital processing, review, transfer, storage, archiving and printing of medical images and patient demographic information.	eUnity™ is a software application that displays medical image data and associated clinical reports. eUnity™ performs operations relating to the transfer, storage, display and measurement of image data. eUnity™ allows users to perform image manipulations, including window/level, rotation,

Indications for Use Statements continued..	organizations within one multi-disciplinary viewer. Users may access the product directly via a web-browser, select mobile devices, healthcare portal or within the Electronic Medical Record (EMR). ICIS® View allows users to perform basic image manipulations and measurements (for example window/level, rotation, zoom, and markups). ICIS® View can optionally be configured for Full Fidelity mode, which is intended for diagnostic use, review and analysis of CR, DX, CT, MR, US images and medical reports. ICIS® View Full Fidelity is not intended to replace full diagnostic workstations and should only be used when there is no access to a workstation. ICIS® View full fidelity is not intended for the display of digital mammography images for diagnosis.	Mobile MIM provides wireless and portable access to medical images. This device is not intended to replace full workstations and should be used only when there is no access to a workstation. The device is not to be used for mammography.	They are indicated for use by the physician to aid in diagnosis, and by medical professionals whenever they would require or desire access to medical images and patient demographic information. MPR and 3D functions allow the user to view 3D image data from perspectives different from that in which it was acquired. Digital subtraction allows a user viewing time series studies to remove densities not enhanced by a contrast medium, highlighting vascular structures.	zoom, measurement and markup. eUnity™ displays both lossless and lossy compressed images. For lossy images, the medical professional user must determine if the level of loss is acceptable for their purposes. Display monitors used for reading medical images for diagnostic purposes must comply with applicable regulatory approvals and with quality control requirements for their use and maintenance. Mammographic images and digitized film screen images must not be reviewed for primary image interpretations..

Table 1: Device Predicate Comparison

E. TECHNOLOGICAL CHARACTERISTICS

Agfa's ICIS® View system is a picture archiving and communication system (PACS), product code LLZ, intended to provide an interface for the display, annotation, review, printing, storage and distribution of multimodality medical images, reports and demographic information for review and diagnostic purposes within the system and across computer networks.

It is a software device running on commercially available computer equipment that allows users to view and modify DICOM compliant medical images and patient information.

Principles of operation and technological characteristics of the new and predicate devices are the same. There is no change to the intended use of the device vs. the predicate devices. The new device is substantially equivalent to the predicate devices (K103785, K022292, & K111164). It is a multidisciplinary viewer that allows the user to securely access patient images and reports from any PACS or vendor-neutral archive. Images and reports can be viewed directly via a web-browser, select mobile device, healthcare portal or Electronic Medical Record (EMR). The new

device includes some of the clinical tools of the predicate devices specifically the functionality to retrieve original lossless renditions of stored images for diagnostic purposes. There are no differences between the device and the predicates (K103785, K022292, & K111164) that impact safety and effectiveness.

F. TESTING

Laboratory testing and software testing (for a moderate level of concern device) using equivalent test protocols as used for Medical Image Management Devices as part of verification and validation under design controls (according to 21 CFR 820.30).

No animal or clinical studies were performed in the development of the new device. No patient treatment was provided or withheld.

1. **ICIS® View vs. Agfa IMPAX (K022292)** - Requirements & Performance of the full fidelity view were evaluated:

To determine substantial equivalence, diagnostic image quality was evaluated by qualified medical professionals comparing images across 3 platforms:

- ICIS® View Desktop – using an FDA clearaed diagnostic monitor
- ICIS® View Mobile – using a calibrated iPad® 3 and iPad® 4
- Agfa's full diagnostic PACS workstation IMPAX 6.6.1 (K022292 predicate)

A sample set of an average of 6 imaging studies per modality (CR, DX, CT, MR, US) were evaluated. Qualified radiologists were asked to provide an acceptable or unacceptable score when comparing the diagnostic quality, including evaluations of contrast, sharpness, artifacts and overall image quality in ICIS® View Full Fidelity mode (both desktop and mobile) to the IMPAX predicate.

2. **Display Device Assessment - TG18 Testing**

The executed validation plan for image quality required calibrated display devices for all assessments.

A direct comparison of all images discussed was conducted such that envrionmental conditions, the evaluator, infrastructure etc. were all identical to make the best comparison assessment possible.

To assess and compare the overall image quality of the display devices used for validation the "Assessment of Display Performance for Medical Imaging Systems" was used (TG18-QC, TG18-BR, TG18-LP).

All results met acceptance criteria.

Performance data including resolution testing and image quality evaluations by qualified radiologists are adequate to ensure equivalence to the predicates.

The product, manufacturing and development processes conform to product safety and medical imaging standards including:

G. PRODUCT STANDARD

- ACR/NEMA PS3.1-3.20: 2011 Digital Imaging and Communications in Medicine (DICOM).

QUALITY MANAGEMENT STANDARDS

- ISO 14971:2012 Application of Risk Management to Medical Devices
- ISO 13485:2003 Medical Devices - Quality Management Systems - Requirements For Regulatory purposes

H. RISK ASSESSMENT AND MANAGEMENT SUMMARY

During the final risk analysis meeting, the risk management team concluded that the medical risk is no greater than with a conventional PACS system previously released to the field.

For ICIS® View there are a total of 20 risks in the broadly acceptable region and two risks in the ALARP region. Zero risks were identified in the Not Acceptable Region. Therefore, the device is assumed to be safe, the benefits of the device are assumed to outweigh the residual risk.

The benefits of ICIS® View are:

- Image and information review capabilities are enhanced over what is offered by traditional film:
  - Immediate access to all available prior patient studies.
  - Time independent access to patient records and information.
  - Simultaneous access to multimodality, multi-departmental image review (a chest x-ray, an, MRI, and CT for example).
- Improved resource utilization of both equipment and staff.
  - Improved communication between local and geographically separated healthcare providers promoting collaborative care.
  - Authorized Users are able to share same patient record and contribute to that record.
- Distribution of clinical data either through digital access, distribution or hardcopy print.

The residual risk of each hazardous situation was analyzed and it was determined that the overall benefits to the patient outweigh the residual risks.

I. CONCLUSIONS

Agfa's ICIS® View system has an Indications For Use statement similar to the predicate devices (K103785, K022292, & K111164). The statements have been combined and simplified. There are no changes to the intended use/indications of the device. Intended uses are the same. The devices have the same technological characteristics.

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Principles of operation and technological characteristics of the new and predicate devices are the same. There is no change to the intended use of the device vs. the predicate devices.

This 510(k) has demonstrated Substantial Equivalence as defined and understood in the Federal Food Drug and Cosmetic Act and various guidance documents issued by the Center for Devices and Radiological Health.